Louisiana Medicaid
Hepatitis C Direct-Acting Antiviral (DAA) Agents

To request authorization for **non-preferred** DAA agents, the prescriber must submit the following documents which must be completed, dated and signed by the prescriber - signature stamps and proxy signatures are not acceptable:

- *Louisiana Uniform Prescription Drug Prior Authorization Form*; **AND**
- *Direct-Acting Antiviral (DAA) Agents Used to Treat Chronic Hepatitis C Virus (HCV) Medication Therapy Worksheet for Louisiana Medicaid Recipients*; **AND**
- *Direct-Acting Antiviral (DAA) Agents Used to Treat Chronic Hepatitis C Virus (HCV) Treatment Agreement for Louisiana Medicaid Recipients*. Each item on the Hepatitis C Therapy Treatment Agreement must be initialed by the recipient, and the agreement must be dated and signed by the recipient.

Additional Point-of-Sale edits may apply.

The authorized generic (AG) of Epclusa® is preferred and does not require authorization. However, point-of-sale (POS) edits may apply~~,~~ (see ~~tables below~~POS document).

***NOTE**: Some medications in this therapeutic class may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations; refer to individual prescribing information for details.*

ALL of the following are required when requesting non-preferred agents:

- The recipient has a diagnosis of chronic hepatitis C (B18.2) and appropriate genotype for agent requested (see Table ~~1~~); **AND**
- The recipient's age (and weight, as applicable) is appropriate for the requested medication (see ~~Table 2~~POS document); **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc. (e.g., for requested non-preferred generic Epclusa® and brand Epclusa®, the preferred authorized generic for Epclusa® is the exact same chemical entity, formulation, strength, etc.); **AND**
- Previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The prescriber states that the recipient is currently using the requested medication, and the request is to complete the patient-specific course of treatment recommended in the prescribing information (see ~~Table 3~~POS document); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication (and all other medications used in a combination hepatitis C virus treatment regimen) has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation

Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**

- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended (including renal function, hepatic state and monitoring for reactivation of hepatitis B); **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested DAA agent.

Duration of authorization approval: Up to maximum duration of therapy depending upon patient-specific factors~~;~~ (see ~~Table 3~~POS document).

~~Table 1.~~ **Genotype Indications**	
Treatment	Indicated for Genotype(s)
Daclatasvir (Daklinza®)	1, 3
Elbasvir/Grazoprevir (Zepatier®)	1, 4
Glecaprevir/Pibrentasvir (Mavyret®)	1, 2, 3, 4, 5, 6
Ledipasvir/Sofosbuvir (Harvoni®; Authorized Generic)	1, 4, 5, 6
Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir (Viekira PAK®)	1
Sofosbuvir (Sovaldi®)	1, 2, 3, 4
Sofosbuvir/Velpatasvir (Epclusa®; Authorized Generic)	1, 2, 3, 4, 5, 6
Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®)	1, 2, 3, 4, 5, 6

~~**Point-of-Sale (POS) Edits for Age, Duration of Therapy and Quantity Limits for DAA Agents**~~

~~**Table 2. Minimum Indicated Age**~~	
~~Treatment~~	~~Minimum Age~~
~~Daclatasvir (Daklinza®)~~	~~≥ 18 years~~
~~Elbasvir/Grazoprevir (Zepatier®)~~	~~≥ 18 years~~
~~Glecaprevir/Pibrentasvir (Mavyret®)~~	~~≥ 12 years[a]~~
~~Ledipasvir/Sofosbuvir (Harvoni®; Authorized Generic)~~	~~≥ 3 years~~
~~Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir (Viekira PAK®)~~	~~≥ 18 years~~
~~Sofosbuvir (Sovaldi®)~~	~~≥ 3 years[b]~~
~~Sofosbuvir/Velpatasvir (Epclusa®; Authorized Generic)~~	~~≥ 18 years~~
~~Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®)~~	~~≥ 18 years~~

~~a. Override provisions are available if recipient does not meet minimum age criteria but weighs at least 45 kg.~~
~~b. Recipient ages 3 – 17 must have genotype 2 or 3 without cirrhosis or with compensated cirrhosis.~~

Table 3. Maximum Duration of Therapy	
Treatment	Duration*
Daclatasvir (Daklinza®) + Sofosbuvir (Sovaldi®)	12 weeks
Elbasvir/Grazoprevir (Zepatier®)	12 – 16 weeks
Glecaprevir/Pibrentasvir (Mavyret®)	8 – 16 weeks
Ledipasvir/Sofosbuvir (Harvoni®; Authorized Generic)	12 – 24 weeks
Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir (Viekira PAK®)	12 – 24 weeks
Sofosbuvir (Sovaldi®)	12 – 48 weeks
Sofosbuvir/Velpatasvir (Epclusa®; Authorized Generic)	12 weeks
Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®)	12 weeks

*Duration ranges depend upon agent-specific factors and patient-specific factors. Refer to individual prescribing information for maxiumum duration. Any duration of therapy greater than the minimum duration listed in this chart must be clinically justified based on the prescribing information and rationale **must be stated on the request**.

Table 4. Maximum Quantity Limit	
Treatment	Maximum Quantity Limit
Daclatasvir (Daklinza®) tablet	1 per day, 28 per rolling 28 days
Elbasvir/Grazoprevir (Zepatier®) tablet	1 per day, 28 per rolling 28 days
Glecaprevir/Pibrentasvir (Mavyret®) tablet	3 per day, 84 per rolling 28 days
Ledipasvir/Sofosbuvir (Harvoni®) 90mg/400mg tablet	1 per day, 28 per rolling 28 days
Ledipasvir/Sofosbuvir (Harvoni®) 45mg/200mg tablet	2 per day, 56 per rolling 28 days
Ledipasvir/Sofosbuvir (Harvoni® 45mg/200mg packet	2 per day, 56 per rolling 28 days
Ledipasvir/Sofosbuvir (Harvoni® 33.75mg/150mg packet	1 per day, 28 per rolling 28 days
Ledipasvir/Sofosbuvir (AG* for Harvoni®) 90mg/400mg tablet	1 per day, 28 per rolling 28 days
Ombitasvir/Paritaprevir/Ritonavir with Dasabuvir (Viekira PAK®) tablet	4 per day, 112 per rolling 28 days
Sofosbuvir (Sovaldi®) 400mg tablet	1 per day, 28 per rolling 28 days
Sofosbuvir (Sovaldi®) 200mg tablet	2 per day, 56 per rolling 28 days
Sofosbuvir (Sovaldi®) 200mg packet	2 per day, 56 per rolling 28 days
Sofosbuvir (Sovaldi®)150mg packet	1 per day, 28 per rolling 28 days
Sofosbuvir/Velpatasvir (Epclusa®; AG*) tablet	1 per day, 28 per rolling 28 days
Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®) tablet	1 per day, 28 per rolling 28 days

*Authorized generic

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Revision	**Date**
Single PDL Implementation	May 2019
Removed Fee-for-Service from title,added wording that AG Epclusa® does not require prior-authorization, moved genotype/age/quantity limit for each agent to tables, modified duration of therapy for Mavyret® per prescribing information, removed other drug-specific criteria wording, added Vosevi genotype/age/duration/quantity limit to tables.	July 2019
Mo~~dified age requirements, modified duration of therapy chart and added quantity limits for new formulations of Harvoni® and Sovaldi®~~ved all point-of-sale information to the POS document	~~January~~ May 202(